

REMARKS

Priority.

Applicants note that the Examiner has noted support for the claimed system comprising three oligonucleotides in Application Ser. No. 08/073,384, filed on June 4, 1993, now U.S. Patent No. 5,541,311 (Office Action, page 2). The Examiner asserts, however, that support for a fluorophore label is not found until Application Ser. No. 08/254,359, filed June 6, 1994, now U.S. Patent No. 5,614,402. Applicants respectfully point out that the use of fluorescent labels (*i.e.*, fluorophore labels) in the claimed systems is included in the earlier filed Application Ser. No. 08/073,384, now U.S. Patent No. 5,541,311. See, *e.g.*, the discussion of the use of fluorescent labels at column 12, line 41, at column 14, line 61, and at column 15, line 16 of the '311 patent. Thus, at least Claim 97 should also be granted the priority date of June 4, 1993.

Specification

Applicants note the Examiner's comments regarding the use of trademarks Cleavase, CFLP, Oligotex and QIAamp in the application, with the indication that such marks should be capitalized and should appear with a generic term (Office Action, page 2-3). Applicants wish to point out that in the preliminary amendment made by substitute specification submitted on July 2, 2002, these and other trademarks were capitalized where they appear, and marks are accompanied by generic terms (*e.g.*, "the enzyme CLEAVASE," "the CFLP method," "the OLIGOTEX kit," and "QIAAMP Blood kits"). Applicants request that the Examiner more specifically identify any trademarks that Applicants are requested to correct.

Claim Objection

The Examiner has objected to Claim 107 for informalities in reciting "wherein said portion said third oligonucleotide" (Office Action, page 3). Without acquiescing to the Examiner's objection, Applicants have amended Claim 107 to recite "wherein said portion of said third oligonucleotide." The amendment to this claim is to correct a typographical error and therefore does not narrow the scope of the claim (*e.g.*, within the meaning of *Festo*¹ or related cases).

¹ *Festo Corp. v. Shokestu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831 (2002)

Claim Rejections

Claims 95-108 are pending in the application. Claims 95, 97, 106 and 107 have been amended. Applicants note that all amendments of claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections, and are made solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),² and without waiving the right to prosecute the unamended claims or similar claims in the future.

The Examiner has rejected Claims 95-108 in an Office Action mailed April 20, 2004. For clarity, the rejections at issue are set forth by number in the order they are addressed herein:

- (1) Claims 95-108 are rejected under 35 U.S.C. § 112, paragraph one, as allegedly being indefinite.
- (2) Claims 95-100, 102, 104 and 105 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Lundeborg, *et al.*, DNA Cell Bio. 1990; 9(4):287-92 (hereinafter "Lundeborg").
- (3) Claims 95-96 and 99-104 are rejected under 35 U.S.C. § 102(e) as being anticipated by Yamamoto, *et al.*, U.S. Patent No. 5,830,643 (hereinafter '643).
- (4) Claims 95-96 are rejected under 35 U.S.C. § 102(e) as being anticipated by Takarada, *et al.*, U.S. Patent No. 5,525,462 (hereinafter '462).
- (5) Claims 95-104 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Yamamoto, *et al.*, U.S. Patent No. 5,830,643 (hereinafter '643), further in view of Stavrianopoulos. U.S. Patent No. 5,989,809 (hereinafter '809).
- (6) Claims 95-96 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Takarada, *et al.*, U.S. Patent No. 5,525,462 (hereinafter '462), further in view of Stavrianopoulos. U.S. Patent No. 5,989,809 (hereinafter '809).

35 U.S.C. § 112

(1) The claims are not indefinite.

The Examiner has rejected Claims 95-108 under 35 U.S.C. § 112, paragraph one, as allegedly being indefinite (Office Action, page 3-4). In particular, the Examiner asserts that the

² 65 Fed. Reg. 54603 (Sept. 8, 2000).

term “system” is indefinite for lacking a definition and for being unclear as to whether it refers to a method or a composition. Applicants respectfully disagree. The term “system” is used throughout the specification and is used numerous times as a general term to describe a variety of assays such as nucleic acid detection or characterization assays. For example, the specification lists a number of prior art systems (*e.g.*, Table 1 on page 5, discussed on page 4, lines 11-13). In each of these instances, the system refers to a collection of components that combine for a particular purpose, such as for PCR, LCR or Q- β replicase systems for nucleic acid analysis. Similarly, the present invention provides systems for nucleic acid analysis (see, *e.g.*, page 40, line 245 - page 41, line 2). The systems of the claims are additionally defined by the specific elements of the systems that are recited, and the relationships of the elements to each other. As such, the systems of the present invention are not indefinite.

Nonetheless, without acquiescing to the Examiner's arguments, Claim 95 and dependent claims are herein amended to recite “A nucleic acid analysis system.”

The Examiner alleges that the limitation in Claim 95 “said at least a portion” in reference to “said third oligonucleotide” lacks antecedent basis (Office Action page 4). Without acquiescing to the Examiner's arguments, Applicants have amended Claim 95 to recite that the first oligonucleotide is complementary to “at least a portion of said third oligonucleotide”.

The Examiner alleges that the limitation in Claims 97-99 “said label” lacks antecedent basis in the claim from which they depend, Claim 95 (Office Action page 4). Without acquiescing to the Examiner's arguments, Applicants have amended Claim 97 (and dependent claims 98-99) to depend from Claim 96, which recites a label. Claim 96 therefore provides proper antecedent bases for the recitation of “said label” in Claims 97-99.

The Examiner alleges that the limitation in Claim 107 “said portion” in reference to “said third oligonucleotide” lacks antecedent basis, asserting that Claim 95 does not recite a portion in reference to a third oligonucleotide (Office Action page 4). Applicants direct the Examiner's attention to the final clause of Claim 95, which recites that the “first oligonucleotide is complementary to at least a portion of said third oligonucleotide” (emphasis added). As such, Claim 95 provides proper antecedent bases for the recitation of “said portion” in Claim 107.

For the reasons recited above, Applicants assert that amended Claims 95-108 are not indefinite and respectfully request that these rejections be removed.

35 U.S.C. § 102

Claim 95 as amended teaches a nucleic acid analysis system comprising, in combination with other recited elements, a third oligonucleotide comprising a hairpin structure comprising a duplex region and a single-stranded region. All other claims depend from Claim 95, either directly or indirectly, and therefore comprise the same limitations. This element was previously found in Claim 106 and dependent Claims 107 and 108, and as such is not new matter. Further, Claims 106-108 were not rejected as being unpatentable under either 35 U.S.C. § 102 or § 103 in view of any of the prior art references cited by the Examiner. As such, it appears that there should be no disagreement that all §102 and §103 rejections should be withdrawn in view of this amendment. Nonetheless, each of the rejections under §102 and §103 are discussed, below.

The claims of the present invention are not anticipated. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP 2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d. 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). As described in more detail below, none of the recited references teaches or suggests all of the elements of claims of the present invention.

(2) The claims are not anticipated by Lundeborg

Claims 95-100, 102, 104 and 105 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Lundeborg (Office Action, page 4). As explained in more detail below, Lundeborg does not set forth each and every element of Claims 95-100, 102, 104 and 105.

As explained above and incorporated by reference here, amended Claim 95 and dependent claims recite a system comprising, in combination with the recited target nucleic acid and the recited first and second oligonucleotides, a third oligonucleotide comprising a hairpin structure comprising a duplex region and a single-stranded region. Lundeborg does not teach or suggest a system comprising a third oligonucleotide comprising a hairpin structure comprising a duplex region and a single-stranded region. Thus, Lundeborg fails to teach or suggest each and every element as set forth in Claims 95-100, 102, 104 and 105 as required under *Verdegaal*, and thus does not anticipate these claims. For these reasons, Applicants respectfully request that these rejections be removed.

(3) The claims are not anticipated by U.S. Patent No. 5,830,643

Claims 95-96 and 99-104 are rejected under 35 U.S.C. § 102(e) as being anticipated by Yamamoto, *et al.*, U.S. Patent No. 5,830,643 (hereinafter '643) (Office Action, page 6). As explained in more detail below, the '643 patent does not set forth each and every element of Claims 95-96 and 99-104.

As explained above and incorporated by reference here, amended Claim 95 and dependent claims recite a system comprising, in combination with the recited target nucleic acid and the recited first and second oligonucleotides, a third oligonucleotide comprising a hairpin structure comprising a duplex region and a single-stranded region. The '643 patent does not teach or suggest a system comprising a third oligonucleotide comprising a hairpin structure comprising a duplex region and a single-stranded region. Thus, the '643 patent fails to teach or suggest each and every element as set forth in Claims 95-96 and 99-104 as required under *Verdegaal*, and thus does not anticipate these claims. For these reasons, Applicants respectfully request that these rejections be removed.

(4) The claims are not anticipated by U.S. Patent No. 5,525,462

Claims 95-96 are rejected under 35 U.S.C. § 102(e) as being anticipated by Takarada, *et al.*, U.S. Patent No. 5,525,462 (hereinafter '462) (Office Action, page 6). As explained in more detail below, the '462 patent does not set forth each and every element of Claims 95-96 and 99-104.

As explained above and incorporated by reference here, amended Claim 95 and dependent claims recite a system comprising, in combination with the recited target nucleic acid and the recited first and second oligonucleotides, a third oligonucleotide comprising a hairpin structure comprising a duplex region and a single-stranded region. The '462 patent does not teach or suggest a system comprising, a third oligonucleotide comprising a hairpin structure comprising a duplex region and a single-stranded region. Thus, the '462 patent fails to teach or suggest each and every element as set forth in Claims 95 and 96 as required under *Verdegaal*, and thus does not anticipate these claims. For these reasons, Applicants respectfully request that these rejections be removed.

35 U.S.C. §103

Applicants note the Examiner's statement regarding common ownership of inventions (Office Action, page 7). All claims are commonly owned, and all claims were commonly owned at the time of invention each claimed invention.

(5) Claims 95-104 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Yamamoto, *et al.*, U.S. Patent No. 5,830,643 (hereinafter '643), further in view of Stavrianopoulos. U.S. Patent No. 5,989,809 (hereinafter '809).

(6) Claims 95-96 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Takarada, *et al.*, U.S. Patent No. 5,525,462 (hereinafter '462), further in view of Stavrianopoulos. U.S. Patent No. 5,989,809 (hereinafter '809).

To establish *prima facie* obviousness of a claimed invention, **all** the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (CCPA 1974). For the reasons recited above and incorporated here by reference, neither the '643 nor the '462 patent teaches or suggests each and every element of the present claims. In particular, neither patent teaches or suggests a nucleic acid analysis system comprising an oligonucleotide that comprises a hairpin structure as recited by amended Claim 95 and dependent claims. The '809 patent cited by the Examiner fails to cure this deficiency of both '643 and '462. The '809 patent does not teach or suggest a nucleic acid analysis system comprising an oligonucleotide that comprises a hairpin structure. Thus, whether taken alone or *in any combination*, the cited references fail to teach all of the limitations of the present claims. As such, the presently claimed invention is nonobvious in view of these references and Applicants respectfully request these rejections be removed.

Form 1449

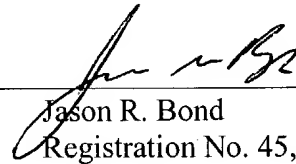
The present application is a divisional application of Application Ser. No. 09/655,378, now U.S. Patent No. 6,673,616. A Form PTO-1449 containing the references from the 1449 Forms of the parent application is enclosed herewith for consideration by the Examiner. Applicants request that the references on this form be printed on the face of any application

issuing from the present case. Copies of the references associated with the Form PTO-1449 are contained in the file of the parent application for the Examiner's review.

CONCLUSION

For the reasons set forth above, it is respectfully submitted that all outstanding issues have been addressed, that all rejections should be removed, and that Applicants' claims should be passed to allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourages the Examiner to call the undersigned collect at (608) 218-6900.

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